DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 22, 2014

Laser Engineering Incorporated
Ms. Laurie Dobbs
Management Representative
475 Metroplex Drive, Suite 401
Nashville, Tennessee 37211

Re: K141908
Trade/Device Name: Dual Switch Adapter
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: September 16, 2014
Received: September 22, 2014

Dear Ms. Dobbs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141908

Device Name
Dual Switch Adapter

Indications for Use *(Describe)*
The intended use for the Dual Switch Adapter is for the vaporization, incision, excision, ablation, or photocaogulation of soft tissue in the surgical specialties of ENT, Gynecology, Laparoscopic Surgery including GYN Laparoscopy, Aesthetic Surgery, Dental and Oral Surgery, Neurosurgery, Orthopedics, General Surgery and Podiatry.

The intended use of the Dual Switch Adapter is for the performance of specific surgical applications in the surgical specialties of ENT, Gynecology, Laparoscopic Surgery including GYN Laparoscopy, Aesthetic Surgery, Dental and Oral Surgery, Neurosurgery, Orthopedics, General Surgery and Podiatry as follows:

Dermatology:

The Dual Switch Adapter is indicated for use in dermatology and plastic surgery for the following applications:
-Ablation, vaporization, excision, and coagulation of soft tissue in the performance of: laser skin resurfacing, laser dermabrasion, and laser burn debridement
-Laser skin resurfacing) ablation and/or vaporization) for the treatment of: wrinkles, rhytids and furrows (including fine lines and texture irregularities).
-Laser skin resurfacing (ablation, and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of:
Keratosis, including actinic and seborrheic keratosis, seborrhoecae vulgares, seborrheci wart and verruUT seborrheica.
Vermillionectomy of the lip
Cutaneous horns
Solar/actinic elastosis
Cheilis, including actinic cheilitis
Lentigines, including lentigo maligna or Hutchinson's malignant freckle
Uneven pigmentation/dyschromia
Acne scars
Surgical scars
Keloids including acne keloidalis nuchae
Hemangiomas (including Buccal, port wine and pygenic granulomas/granuloma pyogenicum/granuloma telangiectaticum)
Tatoos
Telangiectasia
Removal of small skin tumors, including periungual (Koenen) and subungual fibromas
Superficial pigmented lesions
Adenosebaceous hypertrophy or sebaceous hyperplasia
Rhinophyma reduction
Cutaneous papilloma (skin tags)
Milia
Debridement of eczematous or infected skin
Bramous and squamous cell carminoma, including keratoacanthomas, Bowen's disease (Erythroplasia of Queyrat), and Bowenoid Papulosis (BP) lesions
Nevi, including spider, epidermal, and protruding
Neurofibromas
Laser de-epitheliazation
Tricoepitheliomas
Xanthelasma palpebrarum

Syringoma
-Laser ablation, vaporization, and/or excision for complete and partial nail matrixecomy
-Vaporization/coagulation of: benign/malignant vascular/avascular skin lesions, Moh's surgery, Lipectomy, Verrucae and seborrhoecae vulgares, including paronychial, periungual and subungual warts
-Laser incision and/or excision of soft tissue for the performance of upper and lower eyelid blepharoplasty
-Laser incision and/or excision of soft tissue for the creation of receipt sites for hair transplantation

Podiatry

The Dual Switch Adapter is indicated for use in podiatry for the following applications:
-Laser ablation, vaporization, and/or excision of soft tissue for the reduction, removal, and/or treatment of:
Verrucae vulgares/plantar (warts), including paronychial, periungual and subungual warts
Fungal nail treatment
Porokeratoma ablation
Ingrown nail treatment
Neuromas/fibromas, including Morton's neuroma
Debridement of ulcers
Other soft tissue lesions
-Laser ablation, vaporization, and/or excision for complete and partial (nail) matrixectomy

Otolaryngology

The Dual Switch Adapter is indicated for laser incision, excision, ablation and/or vaporization of soft tissue in otolaryngology for the treatment of:
-Choanal atresia
-Leukoplakia, including oral, larynx, uvula, palatal, and upper lateral pharyngeal tissue
-Nasal obstruction
-Adult and juvenile papillomatosis polyps
-Polypectomy of nose and nasal passages
-Lymphangioma removal
-Removal of vocal cord/fold nodules, polyps and cysts
-Removal of recurrent papillomas in the oral cavity, nasal cavity, larynx, pharynx and trachea, including the uvula, palatal, upper lateral pharyngeal tissue, tongue and vocal cords.
-Laser/tumor surgery in the larynx, pharynx, nasal, ear and oral structures and tissue
-Zenker's Deverticulum/pharyngoesophageal diverticulum) endoscopic laser-assisted esophagodiverticulostomy (ELAED)
-Stenosis, including subgottic stenosis
Tonsillectomy (including tonsilar cryptolysis and neoplasma) and tonsil ablation/tonsillotomy
-Pulmonary bronchial and tracheal lesion removal
-Benign and malignant nodules, tumors and fibromas (larynx, pharynx, trachea, tracheobronchial/endobronchial)
-Benign and malignant lesions and fibromas (nose and nasal passages)
-Benign and malignant tumors and fibromas (oral)
-Stapedotomy/Stapedectomy
-Acoustic neuroma in the ear
-Superficial lesions of the ear, including chondrodermatatis nondularis chroniUT helices/Winkler's disease
-Telangiectasia/hemangioma of larynx, pharynx and trachea (includes uvula, palatal, or upper lateral pharyngeal tissue)
-Cordectomy, cordotomy (for the treatment of vocal fold paralysis/vocal fold motion impairment), and cordal lesions of larynx, pharynx and trachea
-Myringotomy/tympanostomy (tympanic membrane fenestration)
-Uvulopalatoplasty and turbinate reduction/ablation
-Septal spur ablation/reduction and septoplasty
-Partial glossectomy
-Tumor resection of oral, subfacial and neck tissue
-Rhinophyma
-Verrucae vulgares (warts)

-Gingivoplasty/gingivectomy

Gynecology and GYN Laparoscopy Indication

The Dual Switch Adapter is indicated for use in gynecology for the following applications:
-Laser incision, excision, ablation and/or vaporization of soft tissue in gynecology for the treatment of:
Conization of the cervix, including cervical intraepithelial neoplasia (CIN), and vulvar and vaginal intraepithelial neoplasia (VIN, VAIN)
Condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowenoid papulosa (BP lesions)
Leukoplakia (vulvar dystrophies)
Incision and drainage (I&D) or Bartholin's and nabothian cysts
Herpes vaporizaton
Urethral caruncle vaporization
Cervical dysplasia
Benign and malignant tumors
Hemangiomas
-Vaporization, incision, excision, ablation or photocoagulation of soft tissue in endoscopic and laparoscopic surgery, including gynecological laparoscopy, for the treatment of:
Endometrial lesions, including ablation of endometriosis
Excision/lysis adhesions
Salpingostomy
Oophorectomy
Fimbrioplasty
Metroplasty
Microsurgery (tubal)
Uterine myomas and fibroids
Ovarian fibromas and follicle cysts
Uterosacral ligament ablation
Hysterectomy

Neurosurgery Indications

The Dual Switch Adapter is indicated for laser incision, excision, ablation and/or vaporizaton of soft tissue in neurosurgery for the treatment of:
-Cranial
Posterior fossa tumors
Peripheral neurectomy
Benign and malignant tumors and cysts, for example, gliomas, meningiomas (including basal tumors), acoustic neuromas, lipomas, and large tumors
Arteriovenous malformation
Pituitary gland tumors (transphenoidal approach)
-Spinal Cord
Incision/excision and vaporization of benign and malignant tumors and cysts
Intra and extradural lesions
Laminectomy/laminotomy/microdiscectomy

Orthopedic Indication

The Dual Switch Adapter is indication for incision, excision, and vaporization of soft tissue in orthopedic surgery, including the following applications:

-Arthroscopy
Meniscectomy
Chondromalacia

Chondroplasty
Ligament release (lateral and other)
Excision of plica
Partial synovectomy
-General
Debridement of traumatic wounds
Debridement of decubitus and diabetic ulcers
Microsurgery
Artificial joint revision
PMMA removal

General and Thoracic Surgery

The Dual Switch Adapter is indication for the incision, excision, and vaporization of soft tissue in general and thoracic surgery, including endoscopic and open procedures. Applications include:

-Debridement of decubitus ulcers stasis, diabetic, and other ulcers
-Mastectomy
-Debridement of burns
-Rectal and anal hemorrhoidectomy
-Breast biopsy
-Reduction mammoplasty
-Cytoreduction for metastatic disease
-Laparotomy and laparoscopic applications
-Mediastinal and thoracic lesions and abnormalities
-Skin tag vaporization
-Atheroma
-Cysts, including sebaceous cysts, pilar cysts, and mucous cysts of the lips
-Pilondial cyst removal and repair
-Abscesses
-Other soft tissue applications

Dental and Oral Surgery

The Dual Switch Adapter is indication for the incision, excision and vaporization of soft tissue in dentisty and oral surgery. Applications include:

-Gingivectomy/removal of hyperplasias
-Gingivoplasty
-Incisional and excisional biopsy
-Treatment of ulcerous lesions, including aphthous ulcers
-Incision of infection when used with antibiotic therapy
-Frenectomy (frenum release)
-Excision and ablation of benign and malignant lesions
-Homeostasis
-Operculectomy
-Crown lengthening
-Removal of soft tissue, cysts and tumors
-Oral cavity tumors and hemangiomas
-Abscesses
-Extraction site hemostasis
-Salivary gland pathologies
-Preproshetic gum preperation
-Leukoplakia

-Partial glossectomy
-Periodental gum resection

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 7– 510(K) SUMMARY

Applicant:

Laser Engineering
475 Metroplex Drive
Suite 401
Nashville, TN 37211
Tel: (615) 550-8282

Contact Person:
Laurie Dobbs
Management Representative
l.dobbs@americansurg.com

Date Prepared: May 27, 2014

Device Name: Dual Switch Adaptor

Proprietary Name:	Dual Switch Adaptor
Classification Name:	Laser Surgical Instrument
Classification:	878.4810
Product Code:	GEX

Predicate Devices:

The Dual Switch Adaptor is substantially equivalent to the following devices.

Device	Manufacturer	510(k) No.
AcuPulse Duo 40WG CO2 Laser System	Lumenis	K100415

Device Description:

The Dual Switch Adaptor is an accessory that can be mounted onto the Ultra MD CO_2 Laser System currently manufactured by Laser Engineering, Inc. under the existing 510K numbers: K881580, K881581, K881582, K881583, K881584, K881585, K881586, K881587, K881588, and K905676.

The Dual Switch Adaptor allows the laser beam to exit the laser vertically through the articulating arm or horizontally through a flexible laser waveguide. The Dual Switch Adaptor provides an alternate delivery system for use in surgical procedures where a flexible delivery system would allow easier and more efficient delivery of laser energy to the targeted tissue. The Dual Switch Adaptor consists of a protective housing that is mounted into the path of the laser beam to divert the energy to the fiber coupler.

The Dual Switch Adaptor is designed to operate at 10.6um and has a broad enough transmission band to accommodate any laser operating in this region.

The laser energy can be supplied traditionally through the articulating arm or into a focusing lens that is coupled into the flexible waveguide, exiting to the tissue at the distal end.

Indications for Use:

The Dual Switch Adaptor is indicated for use with the Ultra MD CO_2 Laser Systems for general and plastic surgery procedures, neurosurgery, and ophthalmology, oral surgery, oto-rhino-laryngology, podiatry, gynecology and urology procedures. It is used to deliver laser energy for incision, excision, ablation, vaporization, and coagulation of soft tissues.

The Dual Switch Adaptor can be used in open surgical procedures and endoscopic procedures.

The use of the Dual Switch Adaptor does not change the indications for use of the Ultra MD CO_2 laser system.

Technological Characteristics Compared to Predicate Device:

After reviewing the technological characteristics (overall design, mechanism of action, mode of operation, and performance characteristics) and the indications for use, it has been determined by Laser Engineering that the Dual Switch Adaptor is substantially equivalent to existing legally marketed devices.

Performance testing:

The Dual Switch Adaptor is bench tested to establish percent transmission, optical alignment and alignment stability